REMARKS

Claims 1 – 11 and 13 – 19 are pending, with Claims 1, 13, and 15 being the independent claims. In the Office Action, the Examiner issued provisional "obviousness-type" double patenting rejections against all the currently pending claims based on the claims of Applicants' parent application, Serial No. 10/768,562. The Examiner also objected to Claim 17 as being in improper dependent form.

With respect to the prior art, the Examiner rejected Claims 1 – 16, 18, and 19 under Section 102 (b) as allegedly anticipated by U.S. Patent No. 6,221,402 to Itoh. Claim 17 was rejected under Section 103 as allegedly obvious from Itoh et al. The Examiner also rejected Claims 1 – 5, 8, 9, 10, 12 – 16, 18 and 19 under Section 102 (b) as allegedly anticipated by U.S. Patent No. 6,740,341 to Holt et al.

Each of the foregoing rejections is respectfully traversed. All statements and assertions of the Examiner pertaining thereto are all contested and are not agreed to in any respect. No argument or assertion of fact, opinion, or the like of the Examiner is agreed to, in whole or in part. Favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Double Patenting Rejections.

The provisional obviousness-type double patenting rejection of Claims 1 – 19 may, of course, be obviated by the submission of an appropriate terminal disclaimer vis-à-vis the '562 application, certain claims of which have been put against certain claims currently pending in the present case. While Applicants do not acknowledge that any of the claims currently pending in the present application are mere obvious variants of any of the noted claims in the '562 application and/or that the prior claims may properly be set up against Applicants' currently pending claims under an obviousness-type double patenting rejection or on any other grounds, Applicants have nonetheless agreed to and hereby do pledge, in the interest of advancing prosecution, to proffer an appropriate terminal disclaimer with respect to the '562 application upon receipt of a Notice of Allowance of the claims in the present application provided, of course, that the subject '562 application does not abandon before Applicants receive their allowance papers, in which case the asserted need for a terminal disclaimer with respect to the '562 application will obviously become a moot point.

In view of Applicants' pledge to proffer an appropriate terminal disclaimer, if

circumstances warrant, per the above, Applicants submit that the provisional obviousness-type double patenting rejections have been satisfactorily addressed and should be withdrawn.

II. Objection To Claim 17.

The Examiner also contends that dependent Claim 17 is of improper form. He asserts Claim 17 does not further limit Claim 16, from which it depends. Applicants respectfully disagree. This error is believed to arise from the fact that Claim 15 (from which Claim 17 ultimately depends) is broadly drawn to a method for making an antibiotic composition. It is not limited to making oral suspensions, although making an oral suspensions is plainly one of the many "embodiments" encompassed within the scope of the method set forth in Claim 15.

Further, Claim 17 does in fact further limit Claims 15 and 16 for the simple reason that, in step (B) of Claim 15, a mixture of core material, solvent, and optional excipients is mixed and granulated in the presence of at least an impeller to form a wet granulation. Claim 16 further specifies that granulation of the materials (along with other effects, such as "particulization" and the like) may also be carried out using a chopper in conjunction with the impeller. However, Claim 16 does not constrain the operation of the chopper to any particular mode of operation, much less a minimum or other speed. Claim 17, however, does constrain the chopper to operate at a speed of at least at 1000 rpm.

From the above, it should be clear beyond peradventure, that Claim 15 does not require chopping at all in the granulation, while Claim 16 is directed to an embodiment of Claim 15 where the granulation is carried out with an impeller in conjunction with a chopper. But no particular speed is set forth in Claim 16 as to operation of the chopper. Claim 17 is directed to the embodiment of Claim 16 where the chopper is set to operate at a speed of at least 1000 rpm for whatever effects it can obtain in conjunction with operation of the impeller, which is preferably, although not necessarily, operated at the same time as the chopper, and wherein either the impeller or the chopper may be required by operation of the granulator, if both are required by the terms of a claim, need not be commenced at the same time and may overlap in their operation, either at the beginning and/or at the end of the same, or may be operated such that their action on the material occurs completely in succession with no overlap at all.

Accordingly, the cascading of scope and the adding of details of various preferred embodiments, moving from Claim 15 through to Claim 16, and then to Claim 17, should be quite evident, as should be the fact that each of these dependent claims adds further requirements to

each preceding claim in accordance with standard claiming practice under US Patent Law. Claim 15 is directed to a method using an impeller, with or without chopping. Claim 16 is directed to a method according to Claim 15 carried out using both an impeller and a chopper, and would cover use of a chopper operated at any desired speed, since none is specified. But Claim 17 requires use of both an impeller and a chopper, in accordance with Claim 16, and that the chopper be "set" to at least 1000 rmp.

Thus, it should be evident that Claim 17 further limits the subject matter of Claim 16.

Accordingly, it is submitted that the objection with regard to Claim 17 is not well-taken, and that the same should be withdrawn.

III. The Itoh Prior Art Rejections.

In regard to the anticipation rejections based on Itoh, Applicants note that independent Claims 1, 13, and 15 have now all been amended to specify, among other things, that the micropellet core comprises clarithromycin. Itoh has not been shown to disclose or suggest the presence of clarithromycin in the cores of micropellets according to the subject claims. In fact, Itoh makes no reference at all to clarithromycin. The mere mention of an "antibiotic" in Itoh is not an anticipation of any/ all antibiotics, any more than the mention of the generic term "dopant" in a prior art reference in the well-known Corning Glass Works case would have been deemed to anticipate all species of the same, including "Germania," for purposes of anticipation under Section 102(b). See, Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F2d 1251, 9 USPQ2nd 1962 (Fed. Cir. 1989).

As the Examiner must know, a basic and oft-used test for determining anticipation is the so-called "infringement" test. Application of this test in the present case would ask the question whether the claimed composition, requiring clarithromycin in the core of the micropellets, would be infringed by the commercial practice of any of the compositions disclosed in Itoh. The clear answer to this question is clearly "no." Itoh does not disclose a pharmaceutical composition with micropellet cores containing clarithromycin. Accordingly, none of the subject claims can properly be rejected under Rule 102(b) based on Itoh, and the anticipation rejections based on Itoh should therefore be withdrawn.

Likewise, the obviousness rejection of Claim 17, which incorporates the limitations of Claim 15, should also be withdrawn. That is, all prior art rejections of the parent independent method Claim 15 have been overcome. Hence, Claim 17, which depends from Claim 15, should

also be deemed allowable and the rejection thereof under Section 103 for alleged obviousness should b withdrawn.

The Section 103 obviousness rejection of Claim 17 based on Itoh, even without the above-discussed amendments to Claims 15 and 17, including addition of Clarithromycin, is said, on page 7 of the Office Action, to be based on the fact that Itoh '402 allegedly describes the use of a granulator in a method of "forming the particles as set out [sic] therein." However, it is not a sufficient basis for obviousness to argue that the Itoh '402 disclosure of a "granulator" operated at 200 rpm for processing a mixture of sildenafil citrate, microcrystalline cellulose and HPMC would have suggested to a person of ordinary skill in the art to use a "chopper" according to Claim 17 at a speed of at least 1000 rpm, especially given the parent Claim 16, which states that a "granulation" step of prior Claim 15 is conducted "in the presence of a chopper." This clearly implies that the chopping may be a distinct operation from granulation, or at least that it can be. That is, the wording of Claims 15-17 clearly implies that any chopping operation may be a part of granulation or may be separate from the same, but plainly they are not equated as being the same.

Nor would the ordinary usage of the term "granulator" or "granulation" imply to a person of ordinary skill that a "setting" appropriate for a granulator would bear any logical or other relation to that of a "chopper." The attached article from Wikipedia about "granulation" processes clearly reveals that, in the pharmaceutical arts, a person of skill would know that granulation may actually mean operations which cause small particles to adhere to one another to make bigger particles (i.e. "accretion" of small particles to bigger ones.)

So there is simply no lawful or common sense basis to suppose that a person of skill aware of Itoh's description of use of granulators would be led to Applicants' claimed use of impellers and choppers to make a wet granulation, much less that a passing reference in Itoh '402 of operating a "granulator" at 200 rpm would somehow suggest to a person of skill that he/she should carry out a method of making clarithromycin micropellets containing core granules as part of a granulation operation employing a chopper set at a speed of at least 1000 rpm. It has not been shown how anything in Itoh '402 have suggested what Applicants call for in Claim 17. Accordingly, the Section 103 rejection of claim 17 based on Itoh is not well taken is contrary to law, and should be withdrawn.

IV. The Holt Prior Art Rejections.

Finally, the Examiner argues that Claims 1 – 5, 8, 9, 10, 12 – 16, 18 and 19 are anticipated by the Holt reference.

As noted above, independent Claims 1, 13, and 15 have been amended to specify that the micropellet core comprises clarithromycin. This is neither disclosed nor suggested by the Holt reference. In fact, Holt, like Itoh, says nothing whatsoever about clarithromycin.

Accordingly, the anticipation rejections based on Holt have been overcome and should be withdrawn.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw all rejections, and to issue a Notice of Allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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